JAN - 4 2001

510K SUMMARY

K003462

Submitted By:	ERBE USA, Inc. 2275 Northwest Parkway Suite 105 Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal
Date Prepared:	11/06/00
Common Name:	Argon Plasma Coagulator (APC) Handle and Applicators for use with ERBOTOM ICC (Intelligent Cut and Coagulation) Series (Multiple Models) Electrosurgical Generator Units and ERBE APC 300 Argon Plasma Coagulator
Trade Name:	ERBE APC Handle and Applicators
Proprietary Name:	ERBE APC Handle and Applicators
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21CFR878.4400)
Product Code:	79GEI

Substantially Equivalent Devices

The ERBE APC Handle and Applicators are substantially equivalent to the following legally marketed devices: Beacon Laboratories, Inc.'s Argon Beam Laparoscopic Electrode, 510(k) Number: K902996 as well as ERBE USA, Inc. 's Hand Switching ESU Pencil, 510(k) Number: K925619; APC Raspatory Handle and Tip, 510(k) Number: K992764; and APC Applicators, 510(k) Number: K992769.

Intended Use and Substantial Equivalence

The ERBE APC Handle with an Applicator is used with an ERBOTOM ICC Electrosurgical Generator and ERBE APC 300 Argon Plasma Coagulator. The APC Handle and Applicators are intended to deliver High Frequency (HF) energy and argon gas to create plasma for coagulation of tissue [i.e., Argon Plasma Coagulator (APC) Coagulation]. The intended use is comparable

Intended Use and Substantial Equivalence Continued

with predicate devices Beacon Laboratories' Argon Beam Laparoscopic Electrode and ERBE' s APC Raspatory Handle and Tip as well as Applicators.

Device Description and Substantial Equivalence

The APC Handle is for connecting an APC Applicator to an argon gas and electrical energy source respectively (i.e., an Argon Plasma Coagulator and Electrosurgical Generator) as well as activating the energy. This function is very similar to the handle for the predicate device ERBE Hand Switching ESU Pencil in that the connection purpose is the same and the activation buttons are equivalent (i.e., They both have buttons to activate the cut and coagulation modes of the equipment). Differences in comparison to the Pencil are as follows. The Pencil is already connected to the tip/applicator, delivers only HF energy, and is disposable. However, these differences with the APC Handle are similarities with predicate device ERBE APC Raspatory Handle and Tip. That is the APC and Raspatory Handles require connection to an applicator/tip, deliver HF energy as well as argon gas/plasma, and are reusable.

The APC Applicators work by using argon gas with a monopolar power source. The electrode in the argon channel of the Applicator is connected to an Electrosurgical Generator through the Handle and Argon Plasma Coagulator. When the HF voltage is high enough in the close proximity of tissue electrically conductive argon plasma forms in the gas stream. This allows the current to flow between the Applicator and the tissue. Current density upon arrival at the tissue surface causes coagulation. The application of the energy to the tissue is uniform and contact free. Some of the APC Applicators have an extension at the tip (i.e., spatula, needle, or hook) that is in some cases electrified. The extensions are used for blunt or electrosurgical dissection of tissue. The mechanism of the APC Applicators is like predicate devices Beacon Laboratories' Argon Beam Electrode as well as ERBE' s APC Raspatory Handle/Tip and Applicators

The APC Handle and Applicators are made of identical or similar materials that are included in the predicate devices. A biological evaluation has been performed on these materials (See Section VII.).

The APC Applicators are provided in various shaft/tip configurations and sizes to accommodate the variations in anatomical structures of patients as well as physician preference in accessing/working in target areas. Tip configurations are as follows: straight, angled/curved, rigid, flexible with or without

Device Description and Substantial Equivalence

permanent or adjustable tip extensions (Note: These extension variations are standard in the industry.). The tip lengths are in a range from 25 mm to 320 mm and diameters vary from 2.3 mm to 6 mm. These physical/dimensional attributes are in the ranges of the predicate devices. The flow rates are also comparable to the predicate devices. Although the rate can be higher than the predicates, this does not have a safety or efficacy impact, in that argon flow is set by the ERBE APC 300 Argon Plasma Coagulator after instrument recognition and then can be adjusted by the physician depending on its specific use on a patient. The pressure at the distal tip is at a maximum of 2000 mbar. Again, this pressure is also in the range of the predicated devices.

The target population is both for laparoscopic and open electrosurgical procedures. The anatomical sites are for various general surgical procedures. These procedures are in many medical specialties and are for various reasons. The target population, anatomical sites, and various general surgical procedures are in the range of the predicate devices.

The APC Handle and Applicators are provided non-sterile. Cleaning and steam sterilization by the customer is required prior to their use. The APC Handle and Applicators are reusable if they are cleaned and sterilized per provided guidelines (Note: See Sections XI and VIII). The supply and use of these devices is comparable with the predicate devices ERBE' s APC Raspatory Handle and Tip as well as Applicators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2001

Mr. John Tartal
Quality Assurance/Regulatory Affairs Manager
ERBE USA, Inc.
2275 Northwest Parkway
Suite 105
Marietta, Georgia 30067

Re: K003462
Trade Name: ERBE APC Handle and Applicators
Regulatory Class: II
Product Code: GEI
Dated: November 6, 2000
Received: November 7, 2000

Dear Mr. Tartal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K003462

DEVICE NAME: APC Handle and Applicators

INDICATIONS FOR USE:

APC Coagulation

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANO
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluatio

Prescription Use ✓ OR Over-The-Co
(Per 21 CFR 801.109) (Optional

Miriam C. Provost for
(Division Sign-Off) C. Witten
Division of General Restorative Devices
510(k) Number K003462